510(k) SUMMARY

JUN 27 2006

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

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DATE PREPARED:

June 1, 2006

DEVICE TRADE NAME:

CARD 43 Cardiotomy Reservoir with phosphorylcholine coating (hereafter referred to as CARD 43)

COMMON NAME:

Hardshell Cardiotomy Reservoir

CLASSIFICATION NAME:

Cardiopulmonary Bypass Blood Reservoir / Cardiopulmonary Bypass Defoamer

UNMODIFIED DEVICE

Synthesis R Hardshell Venous/Cardiotomy Reservoir Mimesys Treated with phosphorylcholine coating (hereafter referred to as Synthesis R) (K022450)

DEVICE DESCRIPTION:

The CARD 43 Cardiotomy Reservoir with phosphorylcholine coating is intended for use in cardiovascular procedures requiring cardiopulmonary by-pass. It defoams, filters and stores the blood coming from the operating field through thoracic, intracardiac and general suction. The device is a modified version of the currently marketed Synthesis R (K022450). The design modifications consist of: eliminating the venous return inlet connector on the top of the reservoir lid, eliminating the venous section of the filtering system and updating of product specifications in the IFU. The modification enables the device to be suited for filtration, defoaming and collection only of blood aspirated from the operative field during cardiopulmonary bypass procedures or postoperatively during chest drainage. Other than this change the CARD 43 and the Synthesis R are similar in their intended use, materials and manufacturing processes.

INDICATION FOR USE:

The CARD 43 is a cardiotomy reservoir specifically designed for cardiovascular procedures requiring cardiopulmonary by-pass. It defoams, filters and stores the blood from the operating field through thoracic, intracardiac and general suction. CARD 43 can be used postoperatively for chest drainage. The CARD 43 should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The CARD 43 is similar to the Synthesis R unmodified device with respect to intended use, materials, biocompatibility and performance of the PC coating, operating principles, control mechanisms, fundamental scientific technology and manufacturing process. The hardshell cardiotomy/venous reservoir of both CARD 43 and Synthesis R share the same technological characteristics, operating principles, and materials except for the design change. The design modifications consist of: eliminating the venous return inlet connector on the top of the reservoir lid, eliminating the venous section of the filtering system and updating of product specifications in the IFU. These design changes make the CARD 43 primarily suited for the collection and removal of microemboli or microaggregates from suctioned blood. The use during cardiopulmonary procedures or postoperatively for chest drainage remains unchanged as a result of the modification. The CARD 43 is substantially equivalent to Synthesis R in intended use, patient population and performance specifications.

The coating of the CARD 43 is identical to the phosphorylcholine coating used on Synthesis R. The cardiotomy reservoir is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:2003 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the CARD 43. The aged device was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity, Sterility, Pyrogenicity, ETO residuals. Package integrity testing was also conducted. The results of this testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the requirements of "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000 – and when applicable, following the ISO 15674 (2001) standard for "Cardiovascular Implants and Artificial Organs – Hardshell Cardiotomies/Venous Reservoirs Systems (with/without filter) and Soft Venous Reservoir Bags" for providing the data necessary to demonstrate both the substantial equivalence with the unmodified device and also for complying with safety and effectiveness requirements. The aged device was tested for *in vitro* hemolysis/cell depletion, structural integrity, mechanical integrity, breakthrough times and volumes, reservoir graduated scale accuracy, residual blood volume, defoaming capacity, filtration efficiency and flaking and leaching studies characterization. The results of these tests met established specifications. This 510(k) cross-references performance data previously submitted in the original Synthesis R 510(k) (K022450) as the above mentioned aspects are not affected by the modification.

CONCLUSIONS:

The CARD 43 device performs in a manner substantially equivalent to the unmodified device with respect to biocompatibility and the functional parameters in common with the unmodified device. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2006

Sorin Group Italia S.R.L.
c/o Mr. Barry Sall
Principal Consultant
200 West Street
Waltham, MA 02451

Re: K061527
CARD 43 Cardiotomy Reservoir with Phosphorylcholine Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Reservoir
Regulatory Class: Class II (Two)
Product Code: DTN
Dated: June 1, 2006
Received: June 2, 2006

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061527

Device Name: CARD 43 Cardiotomy Reservoir with Phosphorylcholine Coating
Indications for Use:

The CARD 43 is a cardiotomy reservoir specifically designed for cardiovascular procedures requiring cardiopulmonary by-pass. It defoams, filters and stores the blood from the operating field through thoracic, intracardiac and general suction. CARD 43 can be used postoperatively for chest drainage. The Card 43 should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Prescription Use __X___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes
Sign-Off)
of Cardiovascular Devices
Number K061527